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Mirov et al.

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(54) **AIR SHOT DETECTION**

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A61M 5/315 (2006.01)
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(52) **U.S. Cl.**
CPC ***A61M 5/365*** (2013.01); ***A61M 5/3146*** (2013.01); ***A61M 5/31511*** (2013.01);
(Continued)

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CPC A61M 5/365; A61M 5/3146; A61M 5/31511; A61M 5/31568; A61M 5/486
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,720,733 A 2/1998 Brown
6,368,314 B1 4/2002 Kipfer et al.
(Continued)

FOREIGN PATENT DOCUMENTS

CA 2 604 498 A1 10/2006
EP 2 777 731 A1 9/2014
(Continued)

OTHER PUBLICATIONS

International Search Report and Written Opinion from the International Searching Authority dated Mar. 5, 2018, for International Application No. PCT/US2017/063768, filed Nov. 29, 2017, 16 pages.
(Continued)

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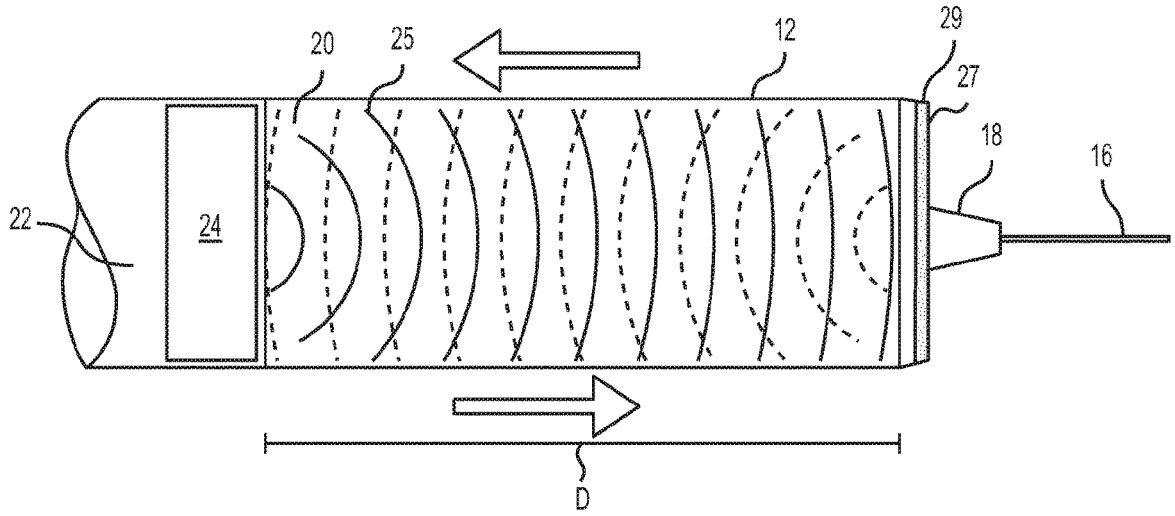
(57) **ABSTRACT**

A medication injection device includes a barrel and a plunger disposed to dispense a fluid from the barrel. A dosage tracking system is coupled to output data indicative of the fluid dispensed. A controller is disposed within the medication injection device and coupled to receive the data from the dosage tracking system. The controller includes logic that when executed by the controller causes the controller to perform operations including determining, based on the data, whether an air shot event occurred while dispensing the fluid.

25 Claims, 9 Drawing Sheets



(51) **Int. Cl.**
A61M 5/31 (2006.01)
A61M 5/48 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 5/31568*** (2013.01); *A61M 5/486* (2013.01); *A61M 2205/0216* (2013.01); *A61M 2205/18* (2013.01); *A61M 2205/215* (2013.01); *A61M 2205/33* (2013.01); *A61M 2205/3344* (2013.01); *A61M 2205/3368* (2013.01); *A61M 2205/3375* (2013.01); *A61M 2205/3569* (2013.01); *A61M 2205/3584* (2013.01); *A61M 2205/3592* (2013.01); *A61M 2205/50* (2013.01); *A61M 2205/52* (2013.01); *A61M 2205/581* (2013.01); *A61M 2205/583* (2013.01); *A61M 2205/587* (2013.01); *A61M 2205/8206* (2013.01); *A61M 2205/8212* (2013.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

8,708,957	B2	4/2014	Jespersen et al.	
9,314,573	B2	4/2016	Nielsen et al.	
2001/0034506	A1	10/2001	Hirschman et al.	
2007/0060820	A1	3/2007	Lofgren et al.	
2007/0235083	A1*	10/2007	Dlugos	A61F 5/0003 137/223
2011/0270214	A1	11/2011	Jorgensen et al.	
2012/0195182	A1	8/2012	Pommereau et al.	
2013/0072897	A1	3/2013	Day et al.	
2014/0288408	A1	9/2014	Deutsch	
2015/0165114	A1*	6/2015	Grant	A61M 5/14586 604/151
2015/0202375	A1	7/2015	Schabbach et al.	
2015/0217059	A1	8/2015	Ashby et al.	
2015/0273129	A1*	10/2015	Freeman	A61M 1/3633 210/698
2015/0289895	A1	10/2015	Gomi et al.	
2016/0022539	A1	1/2016	Daines	
2016/0030663	A1*	2/2016	Adaniya	A61M 5/16877 604/28
2016/0213856	A1*	7/2016	Despa	A61M 5/31568
2018/0001009	A1*	1/2018	Crawford	A61M 1/3661
2019/0022306	A1*	1/2019	Gibson	A61M 5/142

FOREIGN PATENT DOCUMENTS

WO	2007/000680	A2	1/2007
WO	2007024193	A2	3/2007
WO	2010/052275	A2	5/2010
WO	2016/007935	A2	1/2016
WO	WO 2016/062605	*	4/2016
WO	WO 2016/062605	A1	4/2016
WO	2016/122974	A1	8/2016

OTHER PUBLICATIONS

International Application No. PCT/US2017/030068—International Search Report and Written Opinion dated Aug. 11, 2017, 20 pages.
International Preliminary Report on Patentability and Written Opinion dated Oct. 30, 2018 for International Application No. PCT/US2017/023653, filed Mar. 22, 2017, 8 pages.
International Preliminary Report on Patentability and Written Opinion dated Oct. 30, 2018 for International Application No. PCT/US2017/025085, filed Mar. 30, 2017, 9 pages.
International Preliminary Report on Patentability and Written Opinion dated Oct. 30, 2018 for International Application No. PCT/US2017/030068, filed Apr. 28, 2017, 14 pages.
English Translation of Chinese Office Action for corresponding Chinese Patent Application No. 201790000809.1, dated Jul. 11, 2019, pp. 1-3.
English Translation of Chinese Office Action for corresponding Chinese Patent Application No. 201790000809.1, dated Sep. 4, 2019, 2 pages.
European Office Action, dated Mar. 23, 2020, in corresponding European Patent Application No. 17722350.0-1122, 4 pages.

* cited by examiner

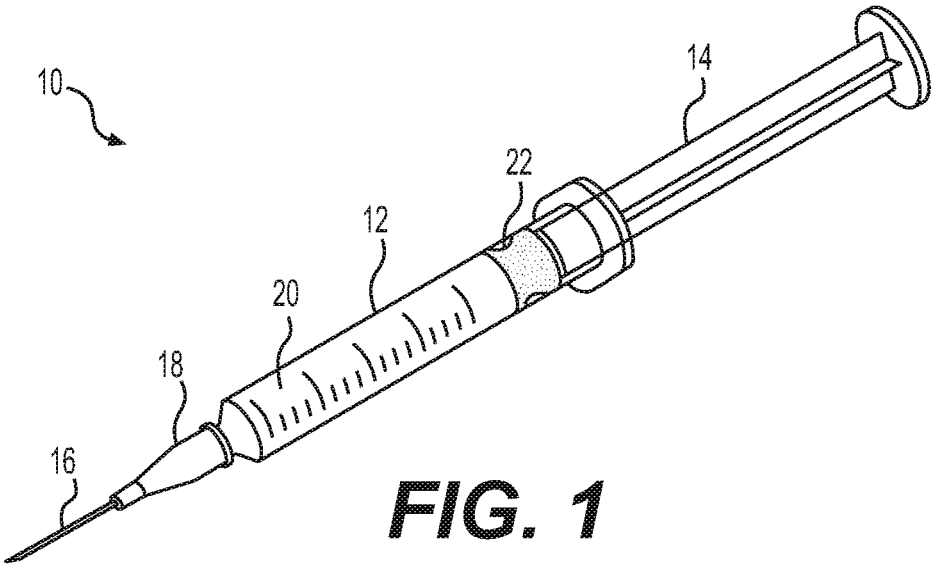


FIG. 1

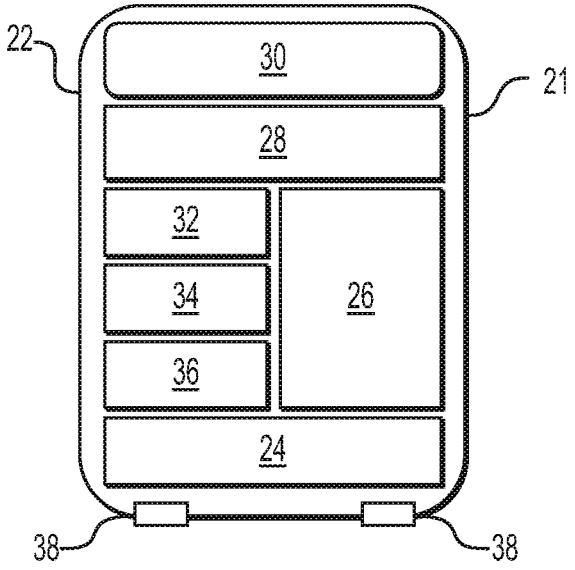


FIG. 2

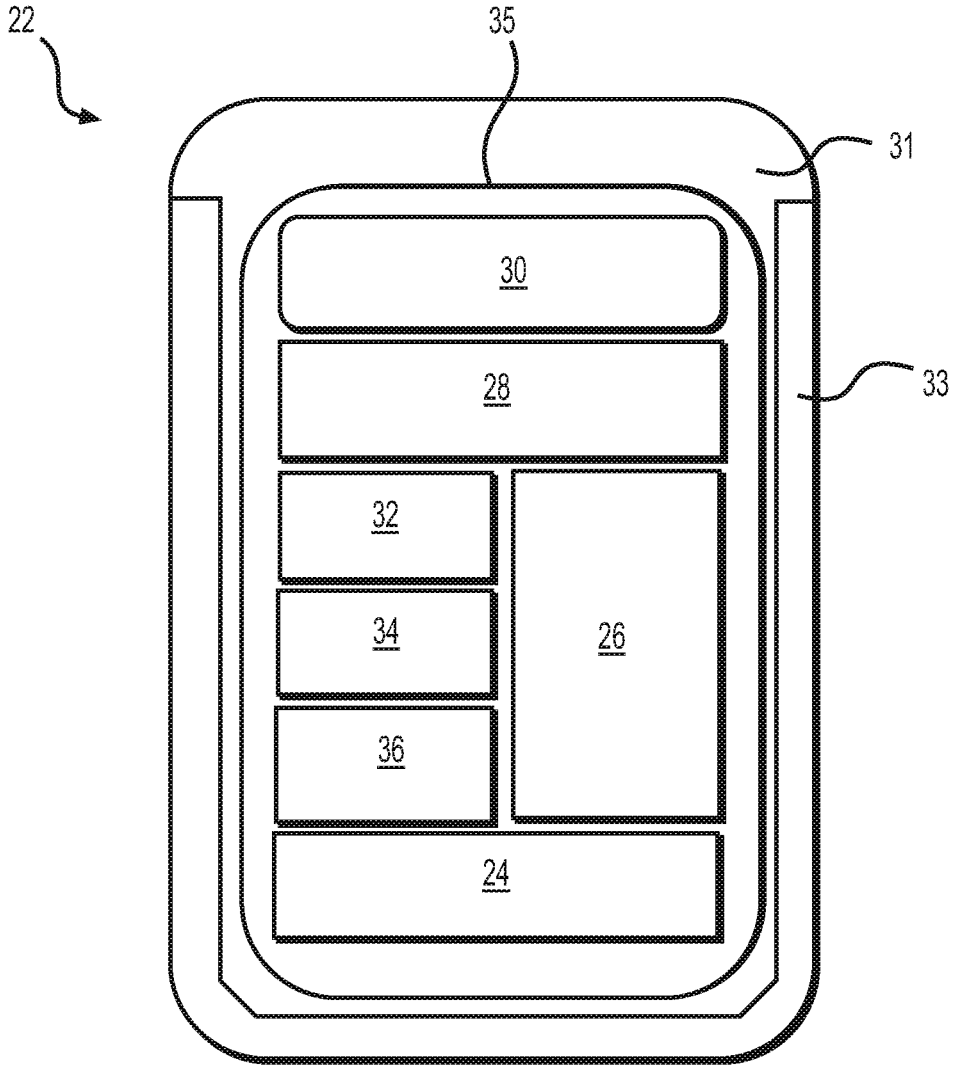


FIG. 3

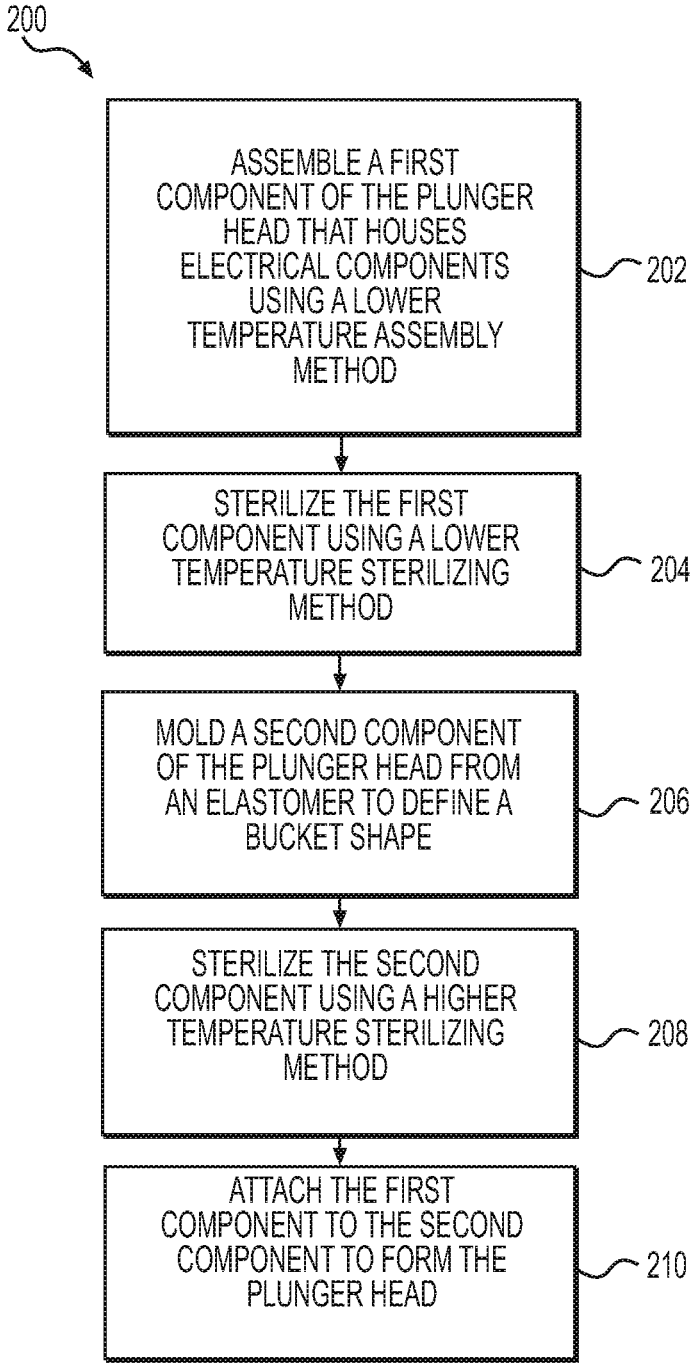

200
ASSEMBLE A FIRST COMPONENT OF THE PLUNGER HEAD THAT HOUSES ELECTRICAL COMPONENTS USING A LOWER TEMPERATURE ASSEMBLY METHOD
202
STERILIZE THE FIRST COMPONENT USING A LOWER TEMPERATURE STERILIZING METHOD
204
MOLD A SECOND COMPONENT OF THE PLUNGER HEAD FROM AN ELASTOMER TO DEFINE A BUCKET SHAPE
206
STERILIZE THE SECOND COMPONENT USING A HIGHER TEMPERATURE STERILIZING METHOD
208
ATTACH THE FIRST COMPONENT TO THE SECOND COMPONENT TO FORM THE PLUNGER HEAD
210

FIG. 4

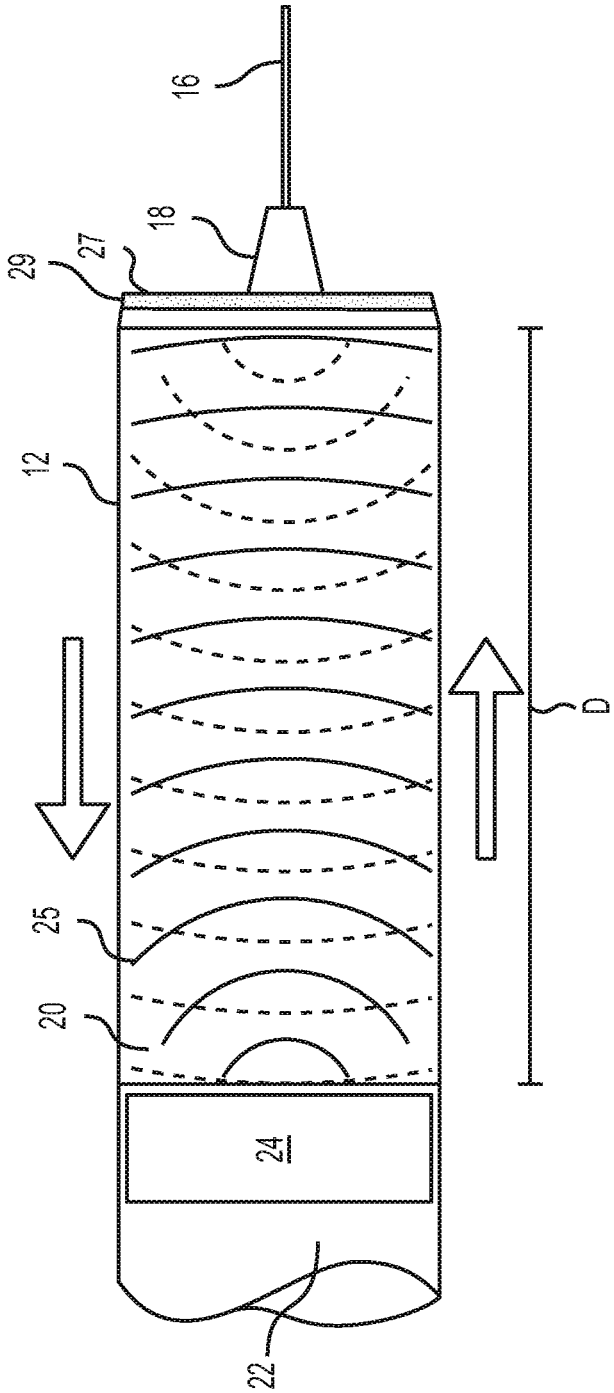


FIG. 5

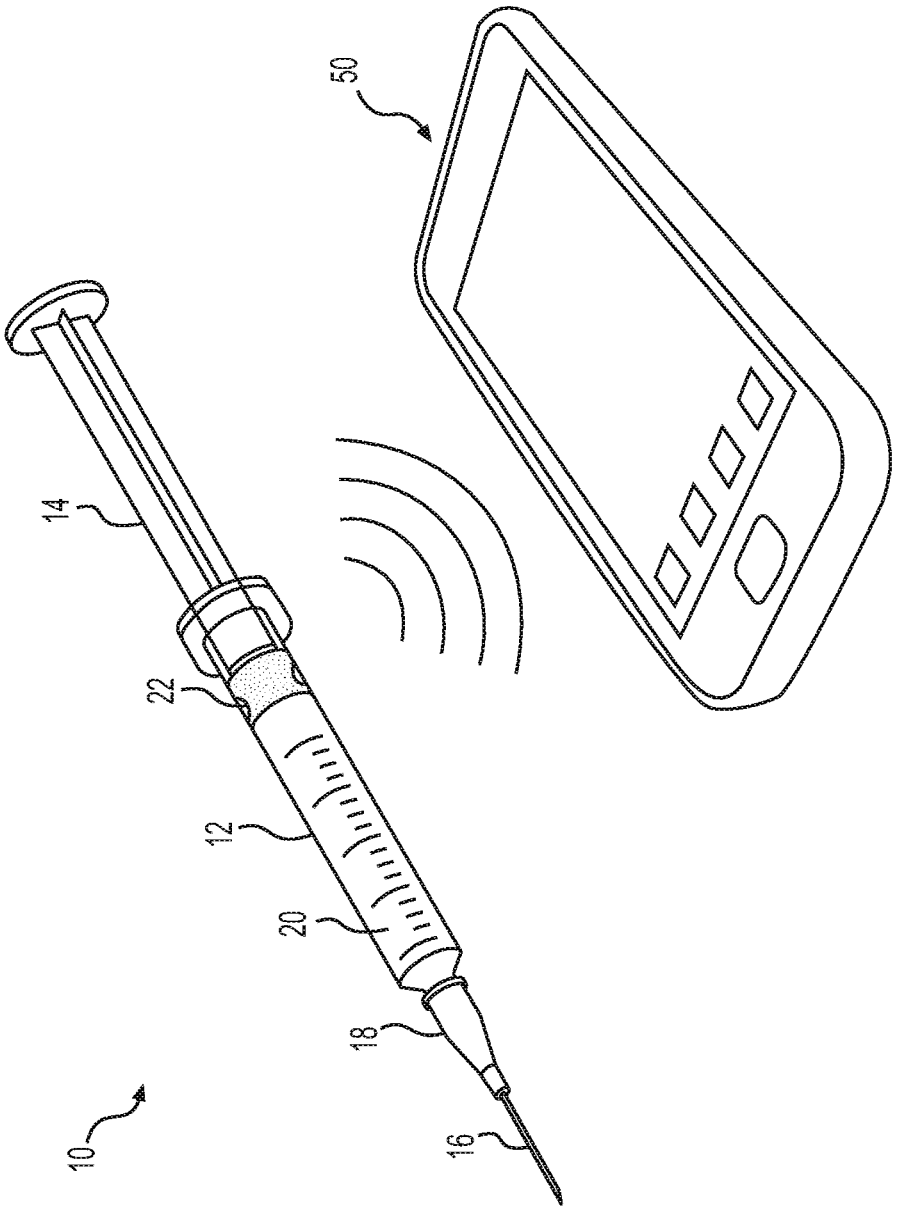


FIG. 6

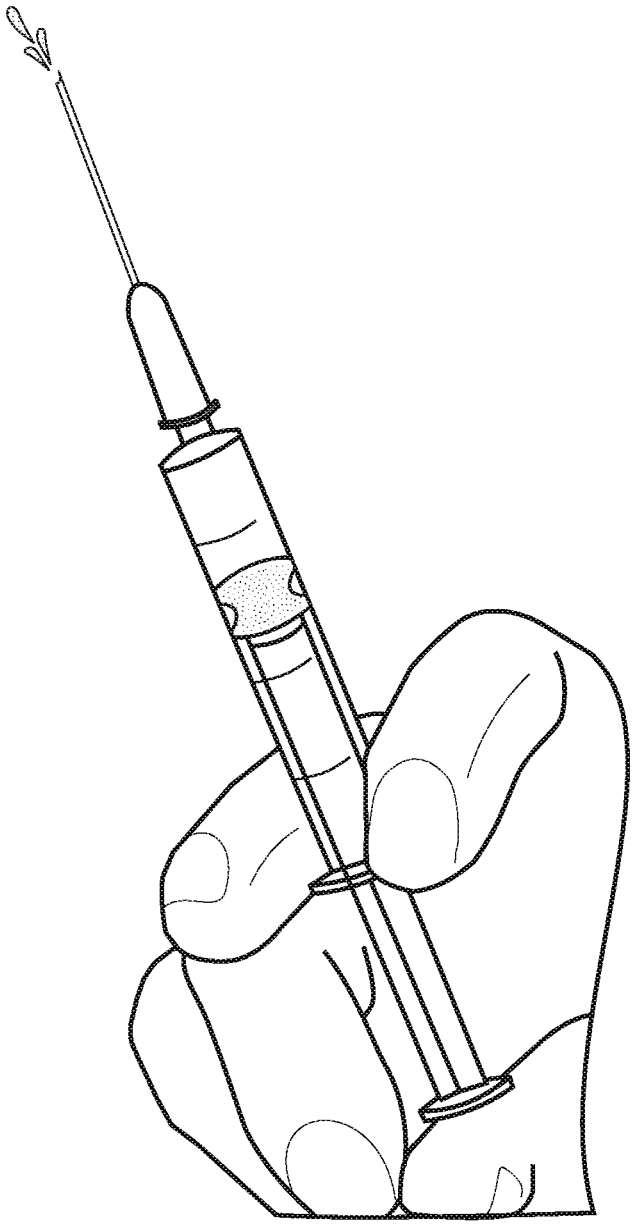


FIG. 7

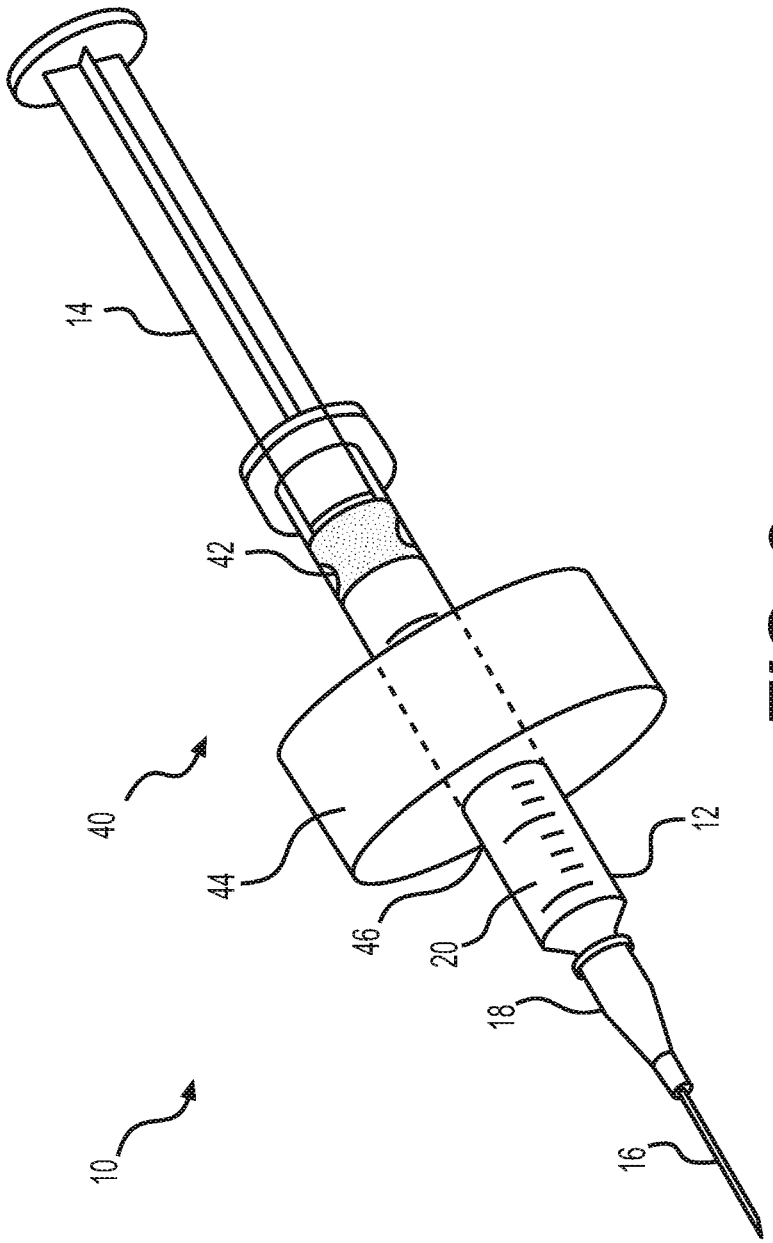


FIG. 8

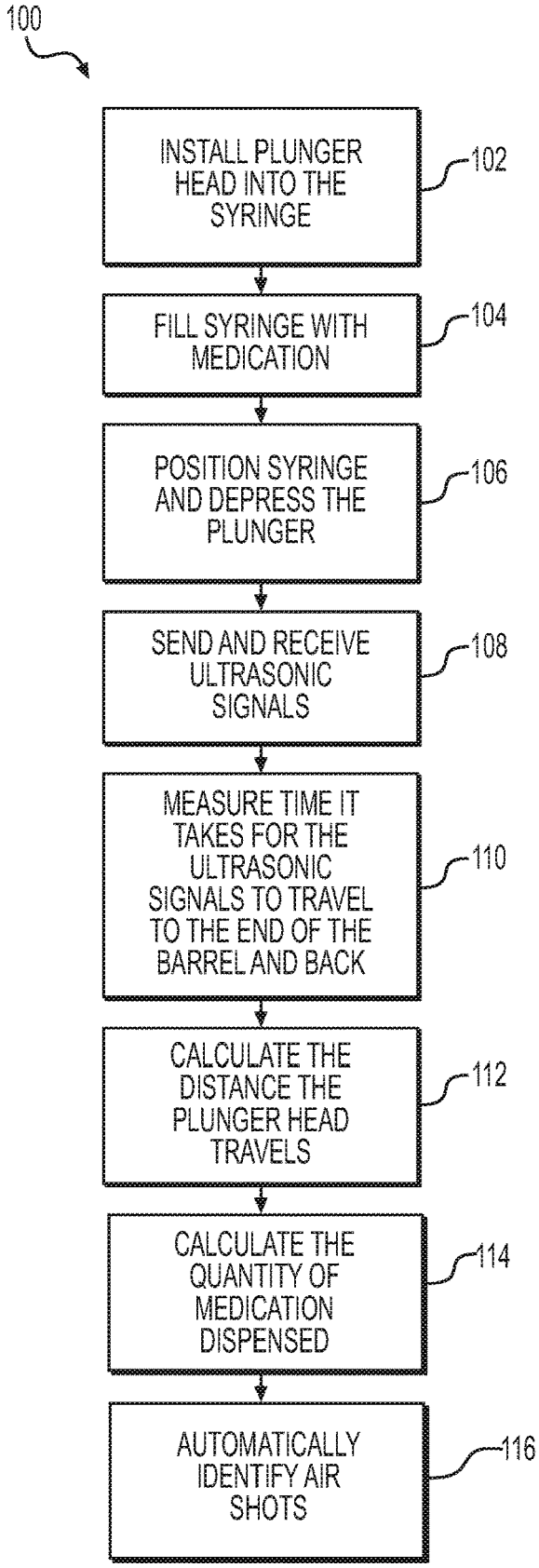

100
INSTALL PLUNGER HEAD INTO THE SYRINGE
102
FILL SYRINGE WITH MEDICATION
104
POSITION SYRINGE AND DEPRESS THE PLUNGER
106
SEND AND RECEIVE ULTRASONIC SIGNALS
108
MEASURE TIME IT TAKES FOR THE ULTRASONIC SIGNALS TO TRAVEL TO THE END OF THE BARREL AND BACK
110
CALCULATE THE DISTANCE THE PLUNGER HEAD TRAVELS
112
CALCULATE THE QUANTITY OF MEDICATION DISPENSED
114
AUTOMATICALLY IDENTIFY AIR SHOTS
116

FIG. 9

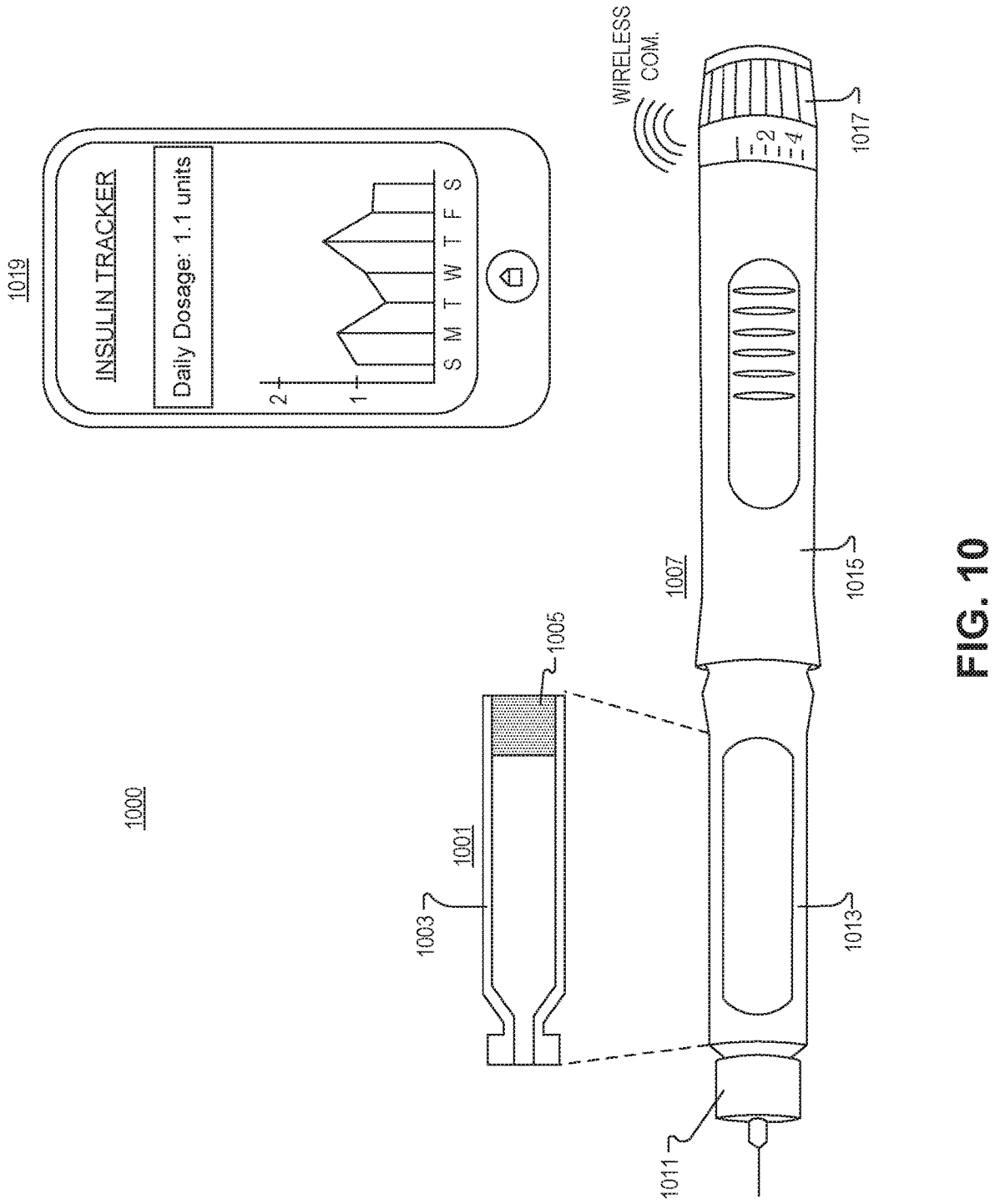

1019
INSULIN TRACKER
Daily Dosage: 1.1 units
2
1
S M T W T F S
WIRELESS COM.
1017
2
4
1007
1015
1005
1001
1003
1013
1011
1000

FIG. 10

AIR SHOT DETECTION

REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 62/329,605, filed on Apr. 29, 2016, and U.S. Provisional Application No. 62/434,662, filed on Dec. 15, 2016, the entire contents of which are hereby incorporated by reference herein.

TECHNICAL FIELD

The present disclosure relates generally to the field of tracking the administration of medication, and more particularly, apparatus and methods for tracking the administration of medication by medication injection devices.

BACKGROUND INFORMATION

Measuring the quantity and recording the timing of a drug's administration is an integral part of many disease treatments. For many treatments, to achieve the best therapeutic effect, specific quantities of a drug may need to be injected at specific times of day. For example, individuals suffering from diabetes may be required to inject themselves regularly throughout the day in response to measurements of their blood glucose. The frequency and volume of insulin injections must be carefully tracked and controlled to keep the patient's blood glucose level within a healthy range. Currently, there are a limited number of methods or devices for automatically tracking the drug administration without requiring the user to manually measure and record the volume, date, and time.

A variety of glucose injection syringes/pens have been developed, but there is much room for significant advancement in the technology. For example, current insulin pens are often disposable, but do not include dosage tracking. A smaller portion of the market is composed of reusable pens which are more expensive, and still don't include good dosage tracking or automatic air shot detection.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting and non-exhaustive embodiments of the invention are described with reference to the following figures, wherein like reference numerals refer to like parts throughout the various views unless otherwise specified. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles being described.

FIG. **1** is a perspective view of a medication injection device, which includes a plunger head, according to an exemplary embodiment.

FIG. **2** is a schematic of the plunger head of FIG. **1**, according to an exemplary embodiment.

FIG. **3** is a cross-sectional schematic illustrating another embodiment of the plunger head of FIG. **1**, according to an exemplary embodiment.

FIG. **4** is a flow chart illustrating a method of manufacturing the plunger head of FIG. **3**, according to an exemplary embodiment.

FIG. **5** is a schematic illustrating the behavior of ultrasonic signals transmitted by the plunger head of FIG. **2** or **3**, according to an exemplary embodiment.

FIG. **6** is a perspective view of the medication injection device of FIG. **1** communicating with a remote device, according to an exemplary embodiment.

FIG. **7** is an illustration of an air shot being performed using a medication injection device, according to an exemplary embodiment.

FIG. **8** is a perspective view of a medication injection device, which includes a plunger head and a cuff, according to an exemplary embodiment.

FIG. **9** is a flow chart illustrating a method of tracking administering of medication by a medication injection device, according to an exemplary embodiment.

FIG. **10** is an illustration of an injection pen system to detect air shots, according to an exemplary embodiment.

DETAILED DESCRIPTION

Embodiments of an apparatus and method for air shot detection are described herein. In the following description numerous specific details are set forth to provide a thorough understanding of the embodiments. One skilled in the relevant art will recognize, however, that the techniques described herein can be practiced without one or more of the specific details, or with other methods, components, materials, etc. In other instances, well-known structures, materials, or operations are not shown or described in detail to avoid obscuring certain aspects.

Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, the appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments.

The present disclosure is directed at detecting an "air shot" (or "prime shot") from a medical injection device (e.g., injection pen or syringe) in order to accurately measure the amount of medication a user injects. Prior to injecting a drug such as insulin typically the user will perform an air shot to remove bubbles or debris from the solution. An air shot includes the user dispensing fluid into the air prior to an injection event into the body. Failure to differentiate, whether the volume dispensed is part of an air shot or injection could lead to more medication than was actually injected being recorded, and this can lead to inaccurate medication injection records.

In some embodiments this air shot detection may be achieved with a plunger head for a medication injection device. The plunger head may include an ultrasonic transducer that sends and receives ultrasonic signals and an antenna. The plunger head may also include a controller that interfaces with the ultrasonic transducer and the antenna and a power source that powers the controller and the ultrasonic transducer. The controller may include logic that when executed by the controller causes the controller to perform operations including receiving data from the ultrasonic transducer and calculating a volume displaced by the plunger head based on the data, and determining, based in part on the data received from the ultrasonic transducer, whether the volume displaced was an air shot.

Other embodiments of the present disclosure may relate to a method of tracking injections of a medication delivered by a medication injection device. The method may include depressing a plunger of the medication injection device and sending and receiving ultrasonic signals from a plunger head installed within a barrel of the medical injection device. The method may also include measuring the time it takes for the

signals to travel through the medication to an end of the barrel and return to the plunger head (i.e., time of flight). The method may further include calculating the distance the plunger head travels based on a change in the time and calculating a volume dispensed based on the distance the plunger head travels. Also the method may include measuring a distance travelled by the plunger head based upon the time of flight of the ultrasonic signals and determining that the air shot event occurred while dispensing the fluid when the distance travelled by the plunger head is below a threshold distance.

In other embodiments, the present disclosure is directed to devices and methods of identifying an air shot from a medication injection device. The method may include calculating a quantity of the medication dispensed from the medication injection device. The devices/methods may further include identifying an air shot of medication using an algorithm (e.g., logic stored in a controller), where the algorithm identifies the air shot event as including a fluid dispensing event where the fluid is deemed not to have been injected into a body (among other events/occurrences). The one or more air shot events may include at least one of an air shot volume event, air shot pattern event, air shot pressure event, a bubble dislodge event, a fluid mixing event, and/or air shot velocity event.

FIG. **1** shows a perspective view of a medication injection device in the form of a syringe **10** designed for ejecting a fluid. Syringe **10** may include a barrel **12**, a plunger **14**, a needle **16**, and a hub **18** connecting needle **16** to barrel **12**. Barrel **12** may be configured to contain a fluid, for example, a medication **20** and syringe **10** may be configured to dispense medication **20** from needle **16** when plunger **14** is depressed. A standard syringe usually contains a plunger head at the end of the plunger that seals the top of the barrel and forces the fluid out the needle when the plunger is depressed. The plunger head for a standard syringe is usually just a piece of molded rubber.

For syringe **10** shown in FIG. **1**, the standard plunger head has been replaced with a smart or intelligent plunger head **22** (e.g., a dosage measurement system) that is configured to measure and register the quantity of medication **20** administered and the time and date of administration. Plunger head **22** may be installed in a standard syringe by withdrawing plunger **14** and removing the standard plunger head and installing smart plunger head **22**. In some embodiments, syringe **10** may be manufactured and supplied with a smart plunger head **22** preinstalled. Smart plunger head **22** may be referred herein as either smart plunger head **22** or plunger head **22**.

Plunger head **22** may be sized to correspond with the size of barrel **12**. For example, plunger head **22** may be formed to fit any size syringe. For example, plunger head **22** may be sized to fit a 1 ml, 2 ml, 3 ml, 5 ml, 10 ml, 20 ml, 30 ml, or 50 ml syringe.

FIG. **2** shows a schematic of plunger head **22**, according to an exemplary embodiment. Plunger head **22** may include a transducer **24**, a controller **26**, a power source **28**, and an antenna (e.g., for near field communication (NFC) or a transceiver **30** (e.g., for BLUETOOTH low energy (BLE) communication). In some embodiments, plunger head **22** may also include a temperature sensor **36**. Temperature sensor **36** may be configured to measure the ambient temperature, which may be generally representative of a temperature of plunger head **22** and/or medication **20**.

Transducer **24** may be an ultrasonic transducer configured to send and receive ultrasonic signals. Controller **26** may be programmed with instructions to control the overall operation of the plunger head. Transceiver **30** may be configured to wirelessly communicate with a remote device (e.g., a smart phone, a glucose monitor, an insulin pump, or a computer) using one or more wireless communication methods. The one or more wireless communication methods may include, for example, radio data transmission, Bluetooth, BLE, near field communication (NFC), infrared data transmission, electromagnetic induction transmission, and/or other suitable electromagnetic, acoustic, or optical transmission methods. Power source **28** may be configured to power transducer **24**, controller **26**, transceiver **30**, temperature sensor **36**, and other electronic components of plunger head **22**.

In some embodiments, as shown in FIG. **2**, the components of plunger head **22** may be at least partially encapsulated in an elastomer **21** (e.g., rubber, ethylene propylene (EPM), Nitrile (NBR), ethylene propylene diene (EPDM), polybutadiene, or polisoprene) that is shaped to define plunger head **22**.

In some embodiments, plunger head **22** may formed of a plurality of components. For example, plunger head **22** may be formed of a first component **31** and a second component **33** that may be fixedly or releasably coupled together such that first component **31** and second component **33** may form plunger head **22**, as shown in FIG. **3**. First component **31** and second component **33** may each take a variety of shapes. FIG. **3** shows a cross-section of one illustrative example where first component **31** may be shaped to define a plug shape while second component **33** may be shaped to define a bucket shape configured to receive the plug shaped first component **31**. When installed in barrel **12**, plunger head **22** may be oriented such that second component **33** sits below first component **31** such that second component **33** may separate first component **31** from medication **20** contained within barrel **12**. As a result, contact with medication **20** within barrel **12** may be limited to second component **33** (i.e., first component **31** may be prevented from contacting medication **20**). Such an arrangement may be advantageous because first component **31** and second component **33** may be manufactured from different materials if desired and the available options of materials for first component **31** may be greater because compatibility with medication **20** may be eliminated as a consideration. Second component **33** may be manufactured from elastomers or other materials commonly used to manufacture plunger heads thus reducing or eliminating compatibility concerns, which may reduce and simplify regulatory hurdles and testing. First component **31** may be manufactured from the same material as second component **33** or from different materials including those which may not be compatible with medication **20**. For example, second component may be formed of an elastomer (e.g., butyl rubber) while first component may be formed of another plastic, elastomer, or rubber (e.g., silicone rubber).

In some embodiments, as shown in FIG. **3**, the electronic components (e.g., transducer **24**, controller **26**, power source **28**, transceiver **30**, and temperature sensor **36**) may be housed in first component **31** while second component **33** may be a simple elastomer mold or liner designed to separate first component **31** from medication **20**. In other words, the electronic components may be isolated from medication **20** within first component **31**. In some embodiments, transducer **24**, transceiver **30**, controller **26**, and power source **28** may be plate cylindrically shaped and arranged in a pancake stack configuration within first component **31**.

The thickness of second component **33** may vary. For example, in some embodiments, the thickness of second component may be about 0.5 millimeters, about 0.6 milli-

meters, about 0.7 millimeters, about 0.8 millimeters, about 0.9 millimeters, about 1 millimeter, about 1.1 millimeter, greater than about 1.1 millimeter, or less than about 0.5 millimeters.

In some embodiments, second component **33** may be preinstalled in barrel **12** and supplied with syringe **10** while first component **31** may be supplied separately and configured to get inserted into second component **33** while it sits in barrel **12**. This arrangement can facilitate the reuse of first component **31** which may house the electronic components. In some embodiments, first component **31** may be coupled to plunger **14** in order to facilitate easy removal of first component **31** after use.

In some embodiments, as shown in FIG. **3**, first component **31** may include, among other things, a structural support system **35**. Structural support system **35** may be designed to prevent unintended deformation of first component **31** so that mechanical tolerances may be maintained with desired ranges. In addition, structural support system **35** may be designed to protect (e.g., prevent damage) of the electronic components due to compressive forces applied to plunger head **22** by plunger **14** when medication **20** is being injected. An upper surface of structural support system **35** may be designed to function as a "push plate" for plunger **14** and may be designed to uniformly distribute the compressive forces applied by plunger **14**.

Structural support system **35** may be, for example, a rigid skeleton, cylinder, container, or frame work that surrounds or encloses one or more of the electronic components. Although FIG. **3** shows structural support system **35** surrounding all the electronic components, it is contemplated that in some embodiments, less than all or a portion of the electronic components may be contained within or surrounded by a boundary of structural support system **35**. In some embodiments, first component **31** may be encapsulated, over-molded, or sealed within a coating (e.g., elastomer, silicone, plastic, or rubber coating).

In some embodiments, one or more of the electronic components may be exposed from first component **31**. For example, in some embodiments, a portion of transducer **24** may be exposed from the bottom of first component **31** so that when first component **31** is inserted within second component **33**, it mates flush with second component **33**.

In some embodiments, first component **31** may also be designed to facilitate proper positioning and orientation of one or more of the electronic components. For example, the shape of first component **31** and second component **33** may be such that when first component **31** is inserted into second component **33**, transducer **24** may be pointed generally down a center of barrel **12** when installed. In some embodiments, second component **33** may also be designed to facilitate proper orientation of antenna/transceiver **30** when receiving first component **31**.

Structural support system **35** may be made generally semi-rigid or rigid and may be formed of a variety of different materials, for example, plastic, elastomers, composites, metals, or combinations thereof.

In some embodiments, first component **31** may also be arranged to provide additional functionality including, for example, power source **28** (e.g., battery). For example, power source **28** may be positioned such that when no compressive forces are applied to first component **31**, then there is no electrical contact between power source **28** and the electronic components, thereby keeping the other electronic components powered down (i.e., conserving power). But when compressive forces are applied to first component **31**, power source **28** or one or more of the other electronic components may be moved and brought into electrical contact thereby powering up. In other words, in some embodiments, power source **28** may be positioned within first component **31**, such that the compressive force applied by plunger **14** acts as an off/off switch, which initiates (e.g., wakes up or powers up) the electronic components of plunger head **22**.

Separating plunger head **22** into first component **31** (that house the electronic components and second component **33** (that contacts the medication) may provide additional advantages. For example, a challenge with monolithic encapsulating or overmolding of electronic components is that the process usually exposes the electronic components to higher temperatures during both the molding step and later sterilization step(s), which may damage the electronic components, in particular, power source **28** (e.g., the battery). By splitting plunger head **22** into separate components (i.e., first component **31** and second component **33**), a lower temperature (e.g., about 60 degrees Celsius or less) series of steps for manufacturing and sterilization can be employed for first component **31**, which houses the electronic components, while a higher temperature (e.g., greater than about 60 degrees Celsius) series of steps for manufacturing and sterilization can be employed for second component **33**, which contacts medication **20**. The first component **31** and second component **33** may then be attached (e.g., by adhesive, bonding, or friction), or another attachment means to form a completed sealed and sterile plunger head **22**.

Although the multiple component arrangements (e.g., first component **31** and second component **33**) is described herein with reference to plunger head **22**, it is contemplated that this multiple or separate component arrangement may be utilized in other applications where electronic components are being packaged (e.g., encapsulated or overmolded) for applications of use where they are alongside sensitive materials (e.g., liquids, medications, chemicals, etc.).

A method **200** of manufacturing plunger head **22** formed of first component **31** and second component **33** will now be explained with reference to FIG. **4**. Method **200** may include, at step **202**, assembling first component **31** of plunger head **22**, which houses the electronic components, using a lower temperature assembly method. Method **200** may also include, at step **204**, sterilizing first component **31** using a lower temperature sterilization method. Method **200** may also include, at step **206**, molding second component **33** of plunger head **22** from an elastomer to define, for example, a bucket shape). Method **200** may also include, at step **208**, sterilizing a second component **33** using a higher temperature sterilization method. Method **200** may also include, at step **210**, attaching first component **31** to second component **33** to form plunger head **22**. First component **31** and second component **33** may then be attached (e.g., by adhesive, bonding, or friction), or another attachment means to form a completed seal and sterile plunger head **22**.

Transducer **24** may be an actuator, piezoelectric element, or speaker-like voice coil configured to generate and send a pressure wave or ultrasonic signal. Transducer **24** may be sized to be slightly smaller than the inner diameter of barrel **12**. As shown in FIG. **5**, transducer **24** may be configured to generate ultrasonic signals **25** (e.g., radiated sound energy waves) and send the ultrasonic signals **25** down barrel **12** toward hub **18** and needle **16**. The ultrasonic signals can travel through medication **20** along the length of barrel **12** and bounce or reflect off an end **27** of barrel **12** and travel back through medication **20** to plunger head **22**. The reflected ultrasonic signals can be received and detected by

transducer **24**. The speed of sound in medication **20** may be a known value and thus a distance D can be calculated very accurately based on the time it takes for a ultrasonic signal to travel down and back from transducer **24**. As plunger head **22** is moved down barrel **12** distance D will change and by knowing the diameter of barrel **12** then the volume of medication **20** dispensed may be calculated based on the change in distance D.

As shown in FIG. **5**, in some embodiments, a porous membrane **29** may be placed within barrel **12** at end **27**. Porous membrane **29** may be designed to allow medication **20** to pass through while providing a surface with good reflective properties for the ultrasonic signals **25** to reflect from. Utilizing porous membrane **29** may improve the accuracy of the reflective wave detection and thereby the distance and volume calculations. It is contemplated that other materials may be used besides a porous membrane. It is also contemplated that the geometry of barrel **12** at end **27** may dictate whether a porous membrane is needed. For example, in some embodiments the geometry of end **27** may be designed to produce the desired reflective properties avoiding the need to porous membrane **29**.

In some embodiments, controller **26** may be configured to use the temperature of medication **20** to compensate for variations in the temperature that would affect the speed of sound within the medication, thus improving the accuracy of the distance and volume calculations.

In some embodiments, controller **26** may be attached to a printed circuit board and may include one or more processors, including for example, a central processing unit (CPU). The processors may include any suitable type of commercially available processor or may be a custom design. Controller **26** may include additional components, for example, non-volatile memory (e.g., a flash memory), volatile memory (e.g., a random access memory (RAM)), and other like components, configured to store information). Controller **26** may be a microcontroller that can be dynamically updated or include logic that is implemented in static hardware.

Controller **26** may be programmed with instructions to control the operation of transducer **24**. Controller **26** may be programmed with instructions to calculate data representative of the volume of medication **20** dispensed. For example, in some embodiments, controller **26** may be programmed to detect and record the reflection times of the ultrasonic signals **25**. Based on the reflection times, controller **26** may track and produce a time profile of the position of transducer **24** (i.e., plunger head **22**). Based on the time profile of the position, controller **26** may be able to identify a first distance D**1** or starting position (e.g., before medication **20** is dispensed), which may correspond with barrel **12** being filed and a second distance D**2** or ending position (e.g., after medication **20** is dispensed), which may correspond with barrel **12** being empty. Controller **26** may then calculate the change in distance between D**1** and D**2** and based off of the change in distance may calculate the volume (i.e., amount or quantity) of medication **20** dispensed.

In some embodiments, medication **20** may include an active medication ingredient and a buffer solution. The concentration of the active medication ingredient may be known or programmed into controller **26** enabling the specific volume of the active medication ingredient to be calculated. In some embodiments, for example, the concentration of the active medication ingredient may be stored in the non-volatile memory of controller **26**. In some embodiments, additional information regarding the medication **20** may also be stored, for example, ultrasonic velocity vs. temperature data.

Transducer **24** and/or controller **26** may be programmed to perform various forms of signal conditioning in order to detect the time of the reflected ultrasonic signals **25**. The signal conditioning may include, for example, amplification, filters, and envelope detection. Transducer **24** and/or controller **26** may use the signal conditioning to determine for example, time to first rising edge or time to maximum reflective value in order to determine the reflection time.

Plunger head **22** may transmit data (e.g., the amount of medication **20** dispensed and time and date it was dispensed) to a remote device (e.g., a smart phone, a glucose monitor, an insulin pump, or a computer) via one or more of the wireless communication methods. For example, as shown in FIG. **6**, plunger head **22** may transmit data to a remote device **50**, which may be a smart phone. Plunger head **22** may have a unique identifier so remote device **50** may be able to identify and process the information received properly. Plunger head **22** may transmit this information to remote device **50** immediately or shortly after the medication is administered or plunger head **22** may store the information until the remote device is paired and within range. The information may be stored, for example, in memory of controller **26**. In some embodiments, plunger head **22** may wait to initiate transmitting of the information to remote device **50** until initiated by remote device **50**. For example, a user may initiate information retrieval on remote device **50**. In some embodiments, remote device **50** may transmit the information to a caregiver (e.g., a doctor) or upload the information to the cloud so it may be saved to the patient's medical history and may be accessed by the caregiver. The ability of a caregiver or a patient to access and review the dose history may improve treatment. For example, the ability of a caregiver to review a diabetic insulin injection history and continuous glucose measurement data may enable the caregiver to adjust the prescribed treatment to improve the therapeutic effect, for example, by better stabilizing the patient's glucose levels.

Plunger head **22** and/or remote device **50** may be programmed to automatically differentiate a portion of the volume dispensed as part of an air shot versus the portion of volume injected into a patient. In other words, plunger head **22** and/or remote device may be programmed to detect and identify an air shot. An air shot may also be referred to as a prime shot or safety shot. An air shot is a common practice associated with medication injection devices (e.g., insulin pens and syringes) and is often a recommended step. An air shot may be defined as priming of the medication injection device by dispensing a small volume (e.g., 2 units) of medication **20** into the air prior to injection. For example, FIG. **7** shows an example of a user performing an air shot. The primary purposes of an air shot are to remove bubbles from the medication within the medication injection device, fill the needle, and clear any potential debris from the needle (e.g., when a needle is reused). It is usually recommended that one or more air shots should be performed until a steady stream is dispensed from the end of the needle.

Failure to differentiate and identify the volume disposed as part of an air shot from the total volume dispense could lead to more medication than was actually injected into a patient being recorded and this can lead to inaccurate medication injection records. By detecting an air shot, the volume of medication dispensed during the air shot can be subtracted from the total volume of medication **20** dispensed to determine the actual volume of medication **20** injected in

a patient. In some embodiments, the volume of the air shot and the volume of the actual injection may be logged and recorded so a caregiver may monitor if recommended procedures (e.g., an air shot) are actually being followed and the frequency at which they are being followed.

An algorithm processing and analyzing the data collected, stored, and/or transmitted by plunger head **22** may be programmed to determine or identify an air shot based on one or more recognizable events (e.g., air shot events) that may be indicative of an air shot. In some embodiments, the algorithm may run locally on plunger head **22** (e.g., using controller **26**). In some embodiments, the algorithm may run on remote device **50**. In some embodiments, the algorithm may run elsewhere (e.g., in the cloud, remote server, or the like) and the data may be uploaded by remote device **50**.

The algorithm may be programmed to identify an air shot based on one or more air shot events where the probability of accurate identification increases based on the number of air shot events utilized in combination. A variety of different air shot events may be detected and/or recognized and utilized by the algorithm as described below.

In some embodiments, for example, one air shot event the algorithm may use to identify an air shot may be an air shot volume event. An air shot volume event may be when a volume of medication is dispensed (e.g., 2 units) that is indicative of an air shot (e.g., air shot volume). For example, if two fluid dispensing events occur in a series, a controller may determine that the first fluid dispensing event is the air shot event if the first quantity of the fluid dispensed is smaller than the second quantity of the fluid dispensed. In some embodiments, an air shot volume event may be identified by controller **26** using the reflection times of the ultrasonic signals **25**. For example, based on the reflection times of the ultrasonic signals **25** a change in the position of plunger head **22** and the dispensed volume may be calculated. When there is a volume dispensed in isolation, which corresponds to an air shot volume, controller **26** may identify this as an air shot volume event. Often, manufacturers of medical injection devices standardize their injection procedures based on industry norms and commonly the procedures instruct the patients to perform a 2-unit air shot before each injection. It is contemplated that the volume programmed to be indicative of an air shot may be adjusted if industry norms changes or other volumes of air shot may be utilized. In addition, the algorithm may utilize a volume range that may extend above or below 2 units (e.g., plus or minus 5%, 10%, 20%, 25%, or more) in order compensate for potential inaccuracy in a patient's operation or inaccuracy in a medication injection device.

Another air shot event the algorithm/controller may use to identify and air shot may be when a pattern of activity (e.g., a sequence of dispensed volumes) is indicative of an air shot. This type of air shot event may be referred to herein as an air shot pattern event. For example, often there may be long periods of inactivity (i.e., no dispensing) followed by a dispensing of a small dose (e.g., 2 units), quickly followed by dispensing of another dose, and then another long period of inactivity. The long period of inactivity typically corresponds to the time in between injections. The first small dose immediately following the inactivity is typically the air shot, and then the second dose is the actual injection. Thus, the algorithm may be programmed to detect when there is a long (or threshold) period of inactivity (e.g., 5 min, 10 min, or more), a small dispensing of fluid, a short gap (e.g., about 5 seconds, about 4 seconds, about 3 seconds, about 2 seconds), and a second volume of medication being dispensed. The algorithm may identify the first volume as an air shot and the second volume as an injection. In other words, a first volume of medication dispensed after a period of inactivity may be recognized as an air shot. This air shot event may be referred to herein as an air shot pattern event.

In situations where there may be more than two dispensed volumes, for example, a first volume, a second volume, and a third volume, the algorithm may be programmed to recognize the first two volumes as air shot, which may be the case if a second air shot was needed to achieve a steady unimpeded stream from the needle.

Another air shot event the algorithm may use to identify an air shot may be when a rate of pressure change of medication **20** within barrel **12** is indicative of an air shot. This type of air shot event may be referred to herein as an air shot pressure event. In order to measure the pressure change, in some embodiments, transducer **24** may be configured to operate as a piezoelectric element, which can output a pressure signal to controller **26** indicative of the present pressure within barrel **12**. In this embodiment transducer **24** is acting as a dosage tracking system. Thus, data representative of pressure over time may be collected by controller **26** when a volume is dispensed from barrel **12**. The pressure over time data may be used to calculate a rate of pressure change. It is generally expected that a faster rate of pressure change will correspond with an air shot, because for an air shot, medication **20** is simply being shot in the air against no back pressure, for example, as shown in FIG. **7**. In contrast, when medication **20** is injected into a patient there is a back pressure caused by the tissue, thus the rate of pressure change during an injection will be slower than that during an air shot. Based on this expectation, controller **26** may be programmed to identify a dispensing event as an air shot pressure event if the rate of pressure change is above a pressure change threshold, or if a first rate of pressure change is greater than a second rate of pressure change in a series of dispensing events.

Another air shot event the algorithm may use to identify an air shot may be when plunger head **22** moves at a velocity indicative of an air shot. This type of air shot event may be referred to herein as an air shot velocity event. For example, a velocity (V) of plunger head **22** during medication dispensing may be calculated using equation (1) shown below, based on the change in distance (d) over time (t).

$$V=\Delta d/t \qquad \text{Equation (1)}$$

It is generally expected that the velocity of plunger head **22** will be greater during an air shot because of the absence of back pressure compared to an injection. Based on this expectation, controller **26** may be programmed to identify a dispensing event as an air shot velocity event if the velocity during the dispensing event is above a velocity threshold, or if the velocity of dispensing first dispensing event in a series of dispensing events is greater than a second dispensing events. The velocity may be indirectly measured with a dosage tracking system (in this embodiment the transducer measuring the position) and output to the controller.

In some embodiments, the algorithm may also be programmed to incorporate and recognize an air shot based on the orientation or the movement of the medical injection device or plunger head **22**. For example, in some embodiments plunger head **22** may include an accelerometer (or other orientation tracker) that controller **26** may utilize to determine and track orientation or movement of plunger head **22** and syringe **10**. For example, the accelerometer output may be used to identify when the syringe **10** is positioned in a generally vertical orientation (e.g., dispensing end of the medication injection device is pointing

upwards), as shown in FIG. **7**, which is commonly the orientation when performing an air shot because it facilitates the bubbles moving to the top and getting removed. In other words the orientation tracker may calculate an orientation of the medication injection device, and output an indication of the orientation in the data sent to the controller. This type of air shot event may be referred to herein as an air shot orientation event.

It is also common to tap or strike the side of barrel **12** before performing an air shot to dislodge bubbles and the tapping or striking motion of the barrel may be detected by the accelerometer and recognized as a bubble dislodge event that is likely to be followed within a threshold period of time by a volume of medication dispensed as an air shot. This type of air shot event may be referred to herein as an air shot bubble dislodge event. For some injections, mixing of the medication is also performed prior to performing an air shot and injection. Often mixing of the medication is done by rolling the syringe back and forth on a table or in between a person's hands. The rolling of the syringe back and forth will likely result in a unique easily identifiable series of outputs from the accelerometer, which the algorithm may utilize to recognize that it is likely that an air shot will be performed shortly after this event within a threshold period of time. This type of air shot event may be referred to herein as an air shot mixing event. Thus, the first fluid dispensing event after a bubble dislodge event (e.g., the characteristic acceleration of tapping/striking the medication injection device) or after a mixing event (e.g., the characteristic acceleration of rolling the syringe) can likely be characterized as an air shot event.

In some embodiments, the algorithm may be programmed to recognize an air shot based on a single air shot event. For example, in some embodiments, the algorithm may be programmed to identify an air shot based an air shot volume. However, utilizing just a single type of air shot event (e.g., based on volume alone) could lead to misidentification of air shots. For example, if the algorithm is programmed to identify a 2-unit dispensed volume (i.e., an air shot volume event) as an air shot it may misidentify a 2-unit injection as an air shot. The other types of air shot events may be utilized in isolation to identify an air shot and in some cases may provide more reliable accuracy. For example, the algorithm may be programmed to recognize an air shot based an air shot pattern event, air shot pressure event, air shot velocity event, air shot orientation event, air shot bubble dislodge event, or air shot mixing event.

In some embodiments, the algorithm may utilize two or more type of the air shot events described herein to recognize an air shot. When the algorithm utilizes multiple events to recognize an air shot it can limit or prevent misidentification of an air shot or failure to identify an air shot. In other words, the more events the algorithm utilizes and detects may increase the probability of accurate air shot detection. The algorithm may utilize any number and combination of the events described herein. For example, in some embodiments the algorithm may be programmed to utilize an air shot pattern event in combination with an air shot volume event. In other embodiments, the algorithm may also incorporate in an air shot pressure event and/or an air shot velocity event to further increase the probability of accurate air shot identification. These combinations of events do not rely on any output from the accelerometer so these combinations of events may be utilized with a plunger head **22** that does not include an optional accelerometer. In contrast, an embodiment of plunger head **22** having an accelerometer may utilize these combinations of events in addition to an air shot orientation event, air shot bubble dislodge event, and an air shot mixing event.

In some embodiments, the algorithm may be programmed to calculate and record an accuracy probability of each recognized air shot based on the number of events and which events were utilized in the determination. In some embodiments, the algorithm may adjust over time which type of events it uses to identify an air shot based on a patient's prior injection routine or behavior. In other words, the algorithm may evaluate prior injection behavior and based on that prior behavior may select the air shot events that will produce the highest likelihood of accurate air shot identification.

It is contemplated that a variety of strategies of programming may be utilized for the algorithm. For example, in some embodiments the algorithm may be programmed to identify an air shot when, for example, two, three, or more of the events are all detected. In other embodiments, the algorithm may be programmed to identify an air shot when at least a portion of the events are detected. For example, the algorithm may be programmed to identify an air shot when two or more out of the total number of events the algorithm is utilizing are detected. Which two or more are detected may vary from air shot to air shot. In some embodiments, the algorithm may be programmed to always require the detection of at one of the events before identifying an air shot.

Now referring back to FIG. **2**, in some embodiments, plunger head **22** may also include a crystal oscillator **32** configured to keep a real time clock (RTC) so that the date and time of each injection may be accurately recorded and stored in memory of controller **26**. Crystal oscillator may be, for example, a 32 KHZ crystal oscillator. In some embodiments, controller **26** may include an internal oscillator (e.g., RC oscillator), which may be calibrated using crystal oscillator **32**. The internal RC oscillator may be, for example, a 10 MHZ RC oscillator. Internal RC oscillator may provide sufficient time accuracy to measure the position (e.g., distance D) of plunger head **22** to within, for example, about 150 microns. In some embodiments, transducer **24** may be used as an oscillator or as a calibrator for the internal RC oscillator. In some embodiments, the frequency of the RC oscillator may be up-converted on controller **26** to a higher frequency. For example, the RC oscillator may be used to drive a higher-frequency phase-locked loop.

In some embodiments, plunger head **22** may be designed to back-interpolate the time of each injection enabling crystal oscillator **32** to be eliminated. In order to maintain the RTC, crystal oscillator **32** may consume a significant amount of power, thus eliminating the crystal oscillator **32** can save a significant amount of power as well as save space.

Plunger head **22** may back-interpolate the time of each injection by relying on the real time clock of the remote device. The method of back-interpolating may start with plunger head **22** taking and logging a series of data samples (e.g., plunger head **22** positions). Plunger head **22** may be programmed to take and log the data samples at an approximately regular interval. The data samples, may be stored, for example in a memory of controller **26** in the order measured. The data samples may be logged and stored into memory with other data values (e.g., calculated injection volume, temperature, etc.). The collection of logged data samples may be transferred/transmitted (e.g., uploaded) to a remote device, which will receive the data samples in the same order. The remote device may rely on the approximately regular interval of the data sample logging to back-interpolate from the actual time at time of transfer, as determined by the RTC of the remote device. By back-interpolating the

approximate time of each data sample logged may be determined. For example, if there were six samples transferred to the remote device and they were known to have been captured at about 60 minute intervals then the remote device may determine the time of each of the six samples were logged working backwards from the time of data transfer. However, this example produces about a 60 minute uncertainty in the calculated time of the data sample points because the time of transfer may not be synchronized with the time of data sample logging. However, plunger head **22** may be programmed to log data samples at a faster frequency to reduce the uncertainty or increase the accuracy. For example, data samples may be logged every 30 minutes, 15 minutes, 10 minutes, 5 minutes, 1 minute, or less than 1 minute.

The approximately regular interval may be determined or maintained by a less accurate, less power consuming, smaller timing device (e.g., an oscillator). It is noted that the reduce accuracy of the timing device may result in the approximately regular interval drifting due to a variety of factors, for example, temperature, voltage, or factory-determined offsets. However, in some embodiments, plunger head **22** may store the factory determined offsets and be programmed with instructions to measure and log the temperature and/or voltage. Controller **26** may be programmed with instructions to use the factory determined offsets and the logged temperatures and voltages to generate a model to correct drift (i.e., change in interval) between the approximately regular intervals caused by variability in the temperature and the voltage. This same method may also be used in other embodiments to correct drift even in a more accurate time tracking system (e.g., a quartz referenced system).

Although the above described back-interpolation and drift correction method is described in reference to plunger head **22**, it is contemplated that this method could be used in other sensor or sampling systems to provide timestamps of useful accuracy for a sequence of sensor samples that do not contain an accurate time reference. This method provides cost, power, and space savings while providing an accurate time reference for a sensor system.

Antenna or transceiver **30** may be used to communicate with a variety of remote devices (e.g., smart phones, glucose monitors, insulin pumps, computers, etc.). Plunger head **22** may transmit the information via any suitable wireless communication method. For example, in some embodiments, plunger head **22** may utilize radio data transmission, BLUETOOTH or BLUETOOTH LOW ENERGY (BLE), near field communication (NFC), infrared data transmission or other suitable method. In some embodiments, information may also be wirelessly transmitted from a remote device to plunger head **22** via antenna **30**. For example, the date and time may be set by writing to controller **26** via the wireless communication.

In some embodiments, plunger head **22** may also include a force sensor **34**. Force sensor **34** may be configured to detect when a force is applied to plunger head **22** via plunger **14**. Force sensor **34** may be, for example, a simple spring-loaded switch that is molded into the plunger head **22**. In some embodiments, transducer **24** may be configured to function as a force sensor thereby eliminating the need for a separate force sensor **34**. For example, transducer **24** may have a piezoelectric element that may detect the dynamic changes in pressure when a user depresses plunger **14**.

Power source **28** may be any suitable power source. For example, power source **28** may be a battery, a capacitor, or the like. In some embodiments, power source **28** may be rechargeable via wireless energy transmission, for example, inductive coupling, resonant inductive coupling, radio frequency (RF) link, or the like. In some embodiments, power source **28** may be a non-rechargeable battery that is configured to last the storage and operational life of plunger head **22**, for which the combined storage and operational life may be about 1 year, about 2 years, about 3 years, or more. For example, in some embodiments, power source **28** may be a watch battery. In some embodiments, where plunger head **22** is a passive device as described herein, power source **28** may be eliminated.

It is common for goods, including medical injection devices, to have a long storage life between the time of manufacture and time of use/sale. Products that include embedded electronics, in particular a battery, it can be a challenge to conserve battery power while the products are in storage. Some products have no on/off switch, buttons, or removable/rechargeable batteries, so the traditional approach of disconnecting or turning off the device while in storage may not be feasible. Also, certain products (e.g., medical injection devices) that include perishable goods (e.g., medication) it may be advantageous to have the product monitor the storage environment (e.g., temperature, light, etc.) and log or store this data and this can't be done if the battery is disconnected.

To address this challenge, plunger head **22** may be designed to enter a low-power sleep mode while in storage. Plunger head **22** may be programmed to enter low-power sleep mode as part of the manufacturing and testing process for plunger head **22** or the medication injection device. When in low-power sleep mode the rate of power consumption may be a fraction of the rate of power consumption for normal operation. While in low-power sleep mode, controller **26** may be programmed with instructions to periodically wake up to measure the temperature. Controller **26** may also log the temperature to create a temperature history. Alternatively, in some embodiments controller **26** may be programmed to log the temperature only when there is a change in temperature, thus saving on data storage. The efficacy of some medications is affected by temperature. For example, insulin is sensitive to hot and cold temperatures. Plunger head **22** thus may monitor the temperature medication **20** through storage and up through use to ensure it stays within an acceptable range. If the temperature of the medication **20** goes outside the acceptable range then plunger head **22** may be configured to send an alert. The type of alert may vary. In some embodiments, plunger head **22** may include a display (not shown in FIG. **2**) and the alert may be a flashing light or a visual indicator. In some embodiments, plunger head **22** may include a speaker and the alert may be auditory, for example, a beeping sound. In some embodiments, the alert may be transmitted to a remote device and the remote device may display a visual alert and/or play an auditory alert.

In some embodiments, plunger head **22** may also be designed to utilize the temperature measurement to transition between modes. For example, a medication injection device that includes plunger head **22** and medication **20** may often be stored at a lower temperature (e.g., below a normal room temperature of about 20 to about 22 degrees Celsius). Subsequently, prior to use, often the temperature will be the medication device, including plunger head **22** and in particular medication **20** will be raised to room temperature because injection of cold fluids can be painful. Thus, usually there will be a transition from a lower temperature to a higher temperature shortly before use thereby triggering a change in the mode of plunger head **22**.

As described above, in lower power sleep mode plunger head **22** can periodically measure the temperature, thus controller **26** may be programmed to detect the temperature change that is expect prior to use and when detected controller **26** may be programmed to transition plunger head **22** from low-power sleep mode into an initialization mode. Controller **26** may be programmed to pair with a remote device while in the initialization mode. After a successful pairing, controller **26** may be programmed to transition plunger head **22** to an operational mode and start sending and receiving ultrasonic waves and measuring the position of transducer **24**. In some embodiments, controller **26** may be programmed to reenter the low-power sleep mode if it is unable pair with a remote device within a certain period of time (e.g., if no remote device is present). Controller **26** may also be programmed to reenter the low-power sleep mode after a period of inactivity (e.g., no measurable change in transducer **24** position after a programmed period of time). Controller **26** may also be programmed to reenter the low-power sleep mode if a subsequent temperature change (e.g., a decrease in temperature from normal room temperature) is detected. Controller **26** may be programmed to transition directly from the low-power sleep mode back to the operational mode if a successful pairing with a remote device has already occurred.

In some embodiments, plunger head **22** may also be configured to detect air bubbles in medication **20**. Air bubbles if injected can be deadly so detection of air bubbles is advantageous. In order to detect air bubbles, transducer **24** of plunger head **22** may be configured to detect small ultrasonic echoes created by the reflection of the ultrasonic waves off the air bubbles in addition to the main echo caused by the end of barrel **12**. Plunger head **22** may be configured to transmit an alert if air bubbles are detected. The alert may be communicated in the same ways as the temperature alert described above.

In some embodiments, plunger head **22** may also be configured to differentiate, verify, and/or identify medication **20** contained in syringe **10**. For example, when barrel **12** is loaded with medication **20**, plunger **14** and plunger head **22** may be pulled all the way back to its stopping point and the distance from plunger head **22** to end **27** of barrel **12** may be known enabling controller **26** to solve for the speed of sound of the fluid, which depends on temperature and density. The temperature may be measured by temperature sensor **36** so the density may be determined and based on the density the amount of solids dissolved in the fluid may also be determined. In addition, the viscosity of the medication **20** may be measured based on the amplitude of the reflected ultrasonic signals **25** because more viscous fluids dissipate more energy. In some embodiments, plunger head **22** may also include electrodes **38** connected to controller **26** configured to measure the conductivity of medication **20**. In some embodiments, the electrodes **38** may protrude out from the surface of plunger head **22** into barrel **12** where the electrodes **38** may contact medication **20**. With the density, conductivity, and viscosity of medication **20** determined, controller **26** may have a sufficient number of properties to profile medication **20**. In some embodiments, the profiling may be configured to differentiate medication **20** in order to determine if it from a prescribed class of medication. In some embodiments, the profiling may be configured to verify that medication **20** is the same as the medication that is prescribed for the patient. In some embodiments, the profiling may be configured to identify the medication **20**.

According to an exemplary embodiment, plunger head **22** as described herein may be combined with a syringe that has been modified to include a piezo linear motor. The piezo linear motor may be incorporated into the wall of the barrel of the syringe and a piezo element may be incorporated into plunger head **22**. The piezo linear motor may be configured to drive or "walk" the plunger head **22** down the barrel of the syringe by driving the piezo element, thereby forcing the medication from the syringe. This embodiment may enable the piezo linear motor to control medication dispensing while plunger head **22** may simultaneously track the amount of medication being dispensed. In some embodiments, plunger head **22** may control the piezo linear motor or plunger head **22** can communication with a remote device that can control the piezo linear motor such that it dispenses a set amount of medication.

FIG. **8** shows a smart syringe system **40**, according to another exemplary embodiment. System **40** may be designed for use with a standard disposable syringe **10** or other medication injection devices. Similar to plunger head **22**, smart syringe system **40** may be configured to measure and register the quantity of medication **20** administered and the date and time of administration. Smart syringe system **40** may include a smart or intelligent plunger head **42**, similar to plunger head **22**, and a cuff **44**. In some embodiments, plunger head **42** may be designed to be disposable after a single use while cuff **44** is reusable. Embodiments of plunger head **42** designed to be disposable after a single use may houses only the minimum number of components to carry out its function while any optional or ancillary components may be housed in cuff **44** to minimize manufacturing cost of plunger head **42**. The manufacturing cost of plunger head **42** may also be minimized by using lower cost components (e.g., transducers, antennas, and controllers) and materials (e.g., rubbers, polymers, plastics) that are less robust and durable, and instead may be designed for shorter operational life spans.

Plunger head **42** may be designed to be supplied with or installed into a disposable syringe **10** and after administering a dose of medication **20**, syringe **10** along with plunger head **42** may be disposed of or recycled. In contrast, cuff **44** may be designed to be reused numerous times. For example, a disposable syringe **10** may be inserted through cuff **44** and after medication **20** is administered; cuff **44** may be removed from the used syringe **10** and be saved for later use.

In some embodiments, both plunger head **42** and cuff **44** may be reusable. For example, after medication **20** is administered by syringe **10**, both plunger head **42** and cuff **44** may be removed and saved for later use.

Plunger head **42** and cuff **44** can come in different sizes so they may be used with any size syringe. For example, plunger head **42** may be sized to fit within the barrel **12** of any size syringe **10** while cuff **44** may be configured to have a passage **46** configured to receive any size barrel **12** of syringe **10**.

Plunger head **42** and cuff **44** (i.e., the smart syringe system **40**) in combination may be configured to have some or all of the same components (e.g., a transducer **24**, a controller **26**, a power source **28**, an antenna **30**, crystal oscillator **32**, force sensor **34**, and a temperature sensor **36**) as plunger head **22** and perform at least all the same operations as plunger head **22**. Some of the components may be housed in plunger head **42** while some of the components may be housed in cuff **44**. To reduce the manufacturing cost of plunger head **42**, as described above, plunger head **42** may be designed to house the minimum number of components to carry out its functions. For example, system **40** may be configured such that all the components that can be housed in cuff **44** are, rather

than plunger head **42**. In some embodiments, such components may include a form of memory for data storage.

According to an exemplary embodiment, plunger head **42** may include the transducer **24**, antenna **30**, and a controller **26** while cuff **44** may also include a separate controller, a power source, and a separate antenna. To reduce complexity, plunger head **42** may be passive (e.g., battery-free) and configured to be controlled and powered by cuff **44** via wireless energy transmission. Cuff **44** may also be configured to communicate with a remote device (e.g., a smart phone, a glucose sensor, an insulin pump, or a computer) thereby enabling the volume of medication and the time and date of administering to be uploaded to another device or the cloud.

In some embodiments, cuff **44** may include a display. Cuff **44** may be configured to display any alerts (e.g., high temperature or improper medication) to the user. Cuff **44** may also display the volume, date, and time after medication has been dispensed. The display may also be configured to allow user input (e.g., touch screen). For example, the user may program in the date, the time, the type of medication or other information.

Plunger head **22** and system **40** described herein may be utilized for a variety of methods for tracking administering of a medication to a patient delivered by syringe. Various methods of utilizing plunger head **22** and system **40** will now be explained with reference to FIG. **9**. In some embodiments, the methods as described herein may be performed by a caregiver (e.g., a doctor or nurse) in a hospital or other inpatient setting. In some embodiments, the methods as described herein may be performed by a caregiver (e.g., a doctor, nurse, or parent) at home or outside a hospital. In some embodiments, the methods as described herein may be performed by the patient. It is contemplated that the methods described herein may be performed in other settings by other individuals.

Plunger head **22** may be utilized for a method **100** of tracking administering of a medication to a patient delivered by a medication injection device (e.g., a syringe), according to an exemplary embodiment. In some embodiments, at step **102**, method **100** may begin by installing plunger head **22** into barrel **12** of syringe **10** (e.g., a disposable syringe). In some embodiments, syringe **10** may be supplied with plunger head **22** already installed. For embodiments corresponding to other medication injection devices (e.g., insulin pen), plunger head **22** may be installed as part of the original manufacturing process, which may also include loading of medication **20** (e.g., insulin).

Optionally, at step **104**, the barrel **12** of the syringe may be filled with the medication **20**. This step may be eliminated for embodiments were the medication **20** comes prefilled. The barrel **12** may be completely filled or only partially with medication **20**.

At step **106**, the syringe may then be positioned for delivery. For example, the needle may be inserted into the skin of the patient or into a drug delivery port connected to the patient. Once in position, the plunger **14** of the syringe **10** may be depressed, which forces plunger head **22** down the barrel **12** and forces the medication **20** out the needle **16**. Optionally, prior to step **106**, method **100** may also include performing an air shot.

In some embodiments, the initial position of plunger head **22** (e.g., the distance between plunger head **22** and end **27**) may be known by plunger head **22**. For example, syringe **10** may be full and plunger head **22** may know the distance between plunger head **22** and end **27** when filled. In some embodiments, if syringe **10** is used multiple times to deliver a medication **20**, the previous position of plunger head **22** may be known from the last measurement stored. In some embodiments, the initial position of plunger head **22** may be measured using plunger head **22** prior to any medication **20** being delivered, as described below.

Prior to and while plunger **14** is being depressed, plunger head **22** may send and receive ultrasonic signals **25** via transducer **24**, at step **108**. Plunger head **22** may send and receive ultrasonic signals **25** the duration of the time the plunger is being depressed. Plunger head **22** may measure a time it takes for each of the ultrasonic signals to travel through the medication to an end of the barrel and return to the transducer, at step **110**. In some embodiments, at least a portion of the ultrasonic signals **25** may be sent and received before any medication **20** is dispensed enabling the initial position of plunger head **22** and initial volume of medication **20** to be calculated.

As described herein, at step **112**, plunger head **22** may calculate the position of plunger head **22** and a distance plunger head **22** travels over the course of dispensing medication **20**. At step **114**, the quantity of medication **20** dispensed may be calculated based on the calculated distance plunger head **22** traveled. At step **116**, method **100** may include automatically identifying an air shot, as described herein. If an air shot is identified then the volume medication dispensed as part of the air shot may be subtracted from the total volume dispensed in order to determine the actual volume of medication **20** injected. As described herein, an algorithm may be utilized that analyzes the data collected to recognize one or more events indicative of an air shot.

For some embodiments of method **100**, the calculation of the quantity of medication dispensed may be performed by remote device **50** (e.g., a smart phone, a glucose sensor, an insulin pump, or a computer). In some embodiments, method **100** may also include transmitting the quantity of the medication dispensed and the time and date the quantity was dispensed to a remote device. In some embodiments, method **100** may also include uploading the quantity of the medication dispensed and the time and date the quantity was dispensed to the cloud. In some embodiments, method **100** may also include sending the quantity of the medication dispensed and the time and date the quantity was dispensed to a caregiver.

For some embodiments, method **100** may also include logging a plurality of data samples (e.g., position of plunger head **22**) at an approximately regular interval and then back-interpolating the time corresponding to each data sample logged to determine the approximate time the quantity of medication **20** was disposed using the RTC maintained by the remote device as a reference time.

Although method **100** is described with reference to plunger head **22**, it may also be performed by system **40**, as described herein.

FIG. **10** is an illustration of an injection pen system **1000** to detect air shots, according to an exemplary embodiment. Pen system **1000** includes drug cartridge **1001**, injection pen **1007**, and processing device **1019** (e.g., a smart phone). Similar to the embodiments described above, before an injection, pen system **1000** may perform an air shot.

Drug cartridge **1001** includes cartridge body **1003** (i.e., a "barrel"), and plunger head **1005**. In the depicted embodiment, plunger head **1005** starts near the rear of drug cartridge **1001** and is pushed forward in drug cartridge **1001** (with a plunger in pen **1007**) to expel medication/fluid from the narrow end of drug cartridge **1001**. Plunger head **1005** may come pre-installed in drug cartridge **1001**, or may be swapped in by a user. Similar to other embodiments, plunger

head **1005** may include any of the electronics described above to send and receive ultrasonic signals, measure pressure, measure velocity, etc.

Injection pen **1007** is a hand-held device and includes needle **1011**, chamber **1013** (to hold drug cartridge **1001**), body **1015** (including a drug dispensing actuator—"plunger"—to push in plunger head **1005** and extract fluid from drug cartridge **1001**), and a drug delivery control switch **1017** (twist the switch to "click" control the dosage). However, as one of ordinary skill in the art will appreciate, injection pen **1007** can take other configurations and have other components. In one embodiment, a dosage measurement system is disposed within pen **1007**, to measure one or more of the quantity of fluid dispensed, pressure in cartridge **1001**, number of injection events, fluid velocity during an injection, etc. In some embodiments, the dosage measurement system may include an accelerometer to measure the orientation of injection pen **1007**, and if a user has tapped/rolled the pen to remove bubbles. The dosage measurement system in injection pen body **1015** may also include mechanical devices to measure the movement of the plunger (e.g., an encoder or pawl/cogwheel) in injection pen body **1015** in order to determine a volume of fluid dispensed. Injection pen body **1015** may include any of the hardware and logic described above in connection with the syringe embodiments, in accordance with the teachings of the present disclosure. These components may be disposed anywhere in injection pen **1000**.

Processing device **1019** (e.g., a smartphone, tablet, general purpose computer, distributed system, servers connect to the internet, or the like) may be coupled to receive data from injection pen **1007** or drug cartridge **1001** to further store/analyze the data. Processing device **1019** may receive the data through any wireless transmission method such as Bluetooth, RFID or the like. In the depicted embodiment, processing device **1019** is a smartphone, and the smartphone has an application running recording how much insulin has been spent from injection pen **1007**. Moreover the application is plotting how much insulin has been injected by the user over the past week.

The processes explained above are described in terms of computer software and hardware. The techniques described may constitute machine-executable instructions embodied within a tangible or non-transitory machine (e.g., computer) readable storage medium, that when executed by a machine will cause the machine to perform the operations described. Additionally, the processes may be embodied within hardware, such as an application specific integrated circuit ("ASIC") or otherwise.

A tangible machine-readable storage medium includes any mechanism that provides (i.e., stores) information in a non-transitory form accessible by a machine (e.g., a computer, network device, personal digital assistant, manufacturing tool, any device with a set of one or more processors, etc.). For example, a machine-readable storage medium includes recordable/non-recordable media (e.g., read only memory (ROM), random access memory (RAM), magnetic disk storage media, optical storage media, flash memory devices, etc.).

The above description of illustrated embodiments of the invention, including what is described in the Abstract, is not intended to be exhaustive or to limit the invention to the precise forms disclosed. While specific embodiments of, and examples for, the invention are described herein for illustrative purposes, various modifications are possible within the scope of the invention, as those skilled in the relevant art will recognize.

These modifications can be made to the invention in light of the above detailed description. The terms used in the following claims should not be construed to limit the invention to the specific embodiments disclosed in the specification. Rather, the scope of the invention is to be determined entirely by the following claims, which are to be construed in accordance with established doctrines of claim interpretation.

What is claimed is:

1. A medication injection device, comprising:

a plunger configured to fit, at least partially, within a barrel to dispense a fluid from the barrel;

a dosage tracking system configured to output data indicative of an amount the fluid dispensed, wherein the dosage tracking system is disposed in a plunger head of the medication injection device and includes an ultrasonic transducer oriented to emit ultrasonic signals through the fluid along a length of the barrel and to receive reflected ultrasonic signals when the plunger is positioned within the barrel, and wherein the data is indicative of a time of flight of the ultrasonic signals; and

a controller disposed within the medication injection device and coupled to the dosage tracking system to receive the data output from the dosage tracking system, wherein the controller includes logic that when executed by the controller causes the controller to perform operations including:

determining, based on the data, whether an air shot event occurred while dispensing the fluid, including:

measuring a distance traveled by the plunger head based upon the time of flight of the ultrasonic signals; and

determining that the air shot event occurred when the distance traveled by the plunger head is below a threshold distance.

2. The medication injection device of claim **1**, wherein the air shot event includes a fluid dispensing event where the fluid is deemed not to have been injected into a body.

3. The medication injection device of claim **1**, wherein the dosage tracking system further includes an orientation tracker to calculate an orientation of the medication injection device and to output an indication of the orientation in the data, and wherein determining, based on the data, whether the air shot event occurred while dispensing the fluid further comprises:

determining that the air shot event occurred when a dispensing end of the medication injection device is pointing upwards while dispensing the fluid.

4. The medication injection device of claim **1**, wherein determining, based on the data, whether the air shot event occurred while dispensing the fluid further comprises:

measuring quantities of the fluid dispensed during a sequence of fluid dispensing events including a first fluid dispensing event and a second fluid dispensing event, the first fluid dispensing event occurring prior the second fluid dispensing event, wherein the quantities include a first quantity of the fluid from the first fluid dispensing event and a second quantity of the fluid from the second fluid dispensing event;

comparing the first quantity of the first fluid dispensing event to the second quantity of the second fluid dispensing event; and

determining that the first fluid dispensing event is an occurrence of the air shot event when the first quantity of the fluid is smaller than the second quantity of the fluid.

5. The medication injection device of claim 1, wherein determining, based on the data, whether the air shot event occurred while dispensing the fluid further comprises:

detecting a threshold period of inactivity of the medication injection device;

detecting a sequence of multiple fluid dispensing events following the threshold period of inactivity; and

determining that a first one of the multiple fluid dispensing events immediately following the threshold period of inactivity is an occurrence of the air shot event.

6. The medication injection device of claim 1, wherein the dosage tracking system is further configured to sense a pressure inside the barrel and the data is indicative of the pressure, wherein determining, based on the data, whether the air shot event occurred while dispensing the fluid further comprises:

measuring rates of change of the pressure inside the barrel during a sequence of fluid dispensing events including a first fluid dispensing event occurring prior to a second fluid dispensing event;

comparing a first rate of pressure change during the first fluid dispensing event to a second rate of pressure change during the second fluid dispensing event; and

determining that the first fluid dispensing event is an occurrence of the air shot event when the first rate of pressure change is greater than the second rate of pressure change.

7. The medication injection device of claim 1, wherein the dosage tracking system further includes an accelerometer configured to measure motion of the medication injection device and outputs an indication of the motion in the data, and wherein the controller includes additional logic that when executed by the controller causes the controller to perform further operations including:

identifying a tapping motion of the medication injection device as a bubble dislodge event; and

determining that a fluid dispensing event following the bubble dislodge event within a first threshold period of time is an occurrence of the air shot event.

8. The medication injection device of claim 1, wherein the controller includes additional logic that when executed by the controller causes the controller to perform further operations including:

identifying a rolling motion of the medication injection device as a fluid mixing event; and

determining that a fluid dispensing event following the fluid mixing event within a threshold period of time is an occurrence of the air shot event.

9. The medication injection device of claim 1, wherein the medication injection device includes at least one of an insulin pen or a syringe.

10. A method of tracking injections of a fluid delivered by a medication injection device, comprising:

measuring dispensing events from the medication injection device with a dosage tracking system;

sending ultrasonic signals with a transducer of the dosage tracking system through the fluid along a length of the medication injection device;

receiving reflected ultrasonic signals with the transducer, wherein data output from the dosage tracking system is indicative of a time of flight between emission and receipt of the ultrasonic signals;

tracking the data indicative of the dispensing events output from the dosage tracking system with a controller coupled to the dosage tracking system; and

determining based on the data whether one or more of the dispensing events includes an air shot event, including:

calculating a volume of fluid dispensed during each of the dispensing events based upon the time of flight of the ultrasonic signals; and

determining that the air shot event occurred during one or more of the dispensing events based on whether the volume of fluid dispensed during each of the dispensing events is less than a threshold volume.

11. The method of claim 10, wherein the dosage tracking system includes an accelerometer, the method further comprising:

measuring motion of the medication injection device with the accelerometer;

identifying a tapping motion of the medication injection device as a bubble dislodge event; and

determining that a next one of the dispensing events following the bubble dislodge event includes the air shot event.

12. The method of claim 11, further comprising:

identifying a rolling motion of the medication injection device as a fluid mixing event; and

determining that the next one of the dispensing events following the fluid mixing event and the bubble dislodge event includes the air shot event.

13. The method of claim 10, further comprising:

calculating an orientation of the medication injection device with an orientation tracker included in the dosage tracking system, wherein the orientation of the medication injection device is included in the data received by the controller; and

determining that the one or more dispensing events includes the air shot event based on the orientation of the medication injection device.

14. The method of claim 10, further comprising:

measuring a period of inactivity of the medication injection device with the dosage tracking system; and

determining based on the data that the one or more dispensing events includes an occurrence of the air shot event when the data indicates the period of inactivity exceeds a threshold period and is followed by one of the one or more dispensing events.

15. The method of claim 10, further comprising:

measuring a pressure inside a barrel containing the fluid with the dosage tracking system during a sequence of the dispensing events including a first dispensing event and a second dispensing event, the first dispensing event occurring prior to the second dispensing event;

comparing a first rate of pressure change during the first dispensing event to a second rate of pressure change during the second dispensing event based, at least in part, the measuring of the pressure; and

determining that the first dispensing event includes the air shot event when the first rate of pressure change is greater than the second rate of pressure change.

16. The method of claim 10, further comprising:

measuring velocities of the dispensing events with the dosage tracking system during a sequence of the dispensing events including a first dispensing event and a second dispensing event, the first dispensing event occurring prior to a second dispensing event, and wherein the velocities includes a first velocity during the first dispensing event and a second velocity during the second dispensing event;

comparing the first velocity during the first dispensing event to the second velocity during the second dispensing event; and

determining that the first dispensing event includes an occurrence of the air shot event when the first velocity is greater than the second velocity.

17. The method of claim **10**, further comprising:

calculating, based on the data received by the controller, a quantity of medication dispensed to a patient by subtracting a quantity of the fluid dispensed during the air shot event from a total quantity of the fluid dispensed.

18. The method of claim **10**, wherein at least one of the dispensing events includes at least one of dialing a dosage or dispensing a volume of fluid.

19. A medication injection device, comprising:

a plunger configured to fit, at least partially, within a barrel to dispense fluid from the barrel;

a dosage tracking system configured to output data indicative of an amount the fluid dispensed; and

a controller disposed within the medication injection device and coupled to the dosage tracking system to receive the data output from the dosage tracking system, wherein the controller includes logic that when executed by the controller causes the medication injection device to perform operations including:

determining, based on the data, whether an air shot event occurred while dispensing the fluid, including:

detecting a threshold period of inactivity of the medication injection device;

detecting a sequence of multiple fluid dispensing events following the threshold period of inactivity; and

determining that a first one of the multiple fluid dispensing events immediately following the threshold period of inactivity is the air shot event.

20. A medication injection device, comprising:

a plunger configured to fit, at least partially, within a barrel to dispense fluid from the barrel;

a dosage tracking system configured to output data indicative of an amount the fluid dispensed, wherein the dosage tracking system is further configured to sense a pressure inside the barrel and the data is indicative of the pressure; and

a controller disposed within the medication injection device and coupled to the dosage tracking system to receive the data output from the dosage tracking system, wherein the controller includes logic that when executed by the controller causes the medication injection device to perform operations including:

determining, based on the data, whether an air shot event occurred while dispensing the fluid, including:

measuring rates of change of the pressure inside the barrel during a sequence of fluid dispensing events including a first fluid dispensing event and a second fluid dispensing event, the first fluid dispensing event occurring prior to the second fluid dispensing event, wherein the rates of change of the pressure inside the barrel include a first rate of pressure change during the first fluid dispensing event and a second rate of pressure change during the second fluid dispensing event;

comparing the first rate of pressure change during the first fluid dispensing event to the second rate of pressure change during the second fluid dispensing event; and

determining that the first fluid dispensing event is an occurrence of the air shot event when the first rate of pressure change is greater than the second rate of pressure change.

21. A medication injection device, comprising:

a plunger configured to fit, at least partially, within a barrel to dispense fluid from the barrel;

a dosage tracking system configured to output data indicative of an amount the fluid dispensed, wherein the dosage tracking system is further configured to measure motion of the medication injection device and output an indication of the motion in the data; and

a controller disposed within the medication injection device and coupled to the dosage tracking system to receive the data output from the dosage tracking system, wherein the controller includes logic that when executed by the controller causes the medication injection device to perform operations including:

identifying, based on the data, a rolling motion of the medication injection device as a fluid mixing event; and

determining that a fluid dispensing event following the fluid mixing event within a threshold period of time is an occurrence of an air shot event.

22. At least one machine-accessible storage medium having stored thereon instructions, which when executed by a machine cause the machine to perform operations comprising:

measuring dispensing events of a fluid from a medication injection device with a dosage tracking system;

measuring a period of inactivity of the medication injection device with the dosage tracking system;

tracking data indicative of the dispensing events output from the dosage tracking system with a controller coupled to the dosage tracking system; and

determining based on the data whether one or more of the dispensing events includes an air shot event, including:

determining based on the data that the one or more dispensing events includes an occurrence of the air shot event when the data indicates the period of inactivity exceeds a threshold period and is followed by one of the one or more dispensing events.

23. At least one machine-accessible storage medium having stored thereon instructions, which when executed by a machine cause the machine to perform operations comprising:

measuring dispensing events of a fluid from a medication injection device with a dosage tracking system, including:

measuring a pressure inside a barrel containing the fluid with the dosage tracking system during a sequence of the dispensing events including a first dispensing event and a second dispensing event, the first dispensing event occurring prior to the second dispensing event;

tracking data, including the pressure, indicative of the dispensing events output from the dosage tracking system with a controller coupled to the dosage tracking system; and

determining based on the data whether one or more of the dispensing events includes an air shot event, including:

comparing a first rate of pressure change during the first dispensing event to a second rate of pressure change during the second dispensing event based, at least in part, on the pressure; and

determining that the first dispensing event includes the air shot event when the first rate of pressure change is greater than the second rate of pressure change.

24. At least one machine-accessible storage medium having stored thereon instructions, which when executed by a machine cause the machine to perform operations comprising:

measuring dispensing events of a fluid from a medication injection device with a dosage tracking system, including:

measuring velocities of the dispensing events with the dosage tracking system during a sequence of the dispensing events including a first dispensing event and a second dispensing event, the first dispensing event occurring prior to the second dispensing event, and wherein velocities includes a first velocity during the first dispensing event and a second velocity during the second dispensing event;

tracking data indicative of the dispensing events output from the dosage tracking system with a controller coupled to the dosage tracking system; and

determining based on the data whether one or more of the dispensing events includes an air shot event, including:

comparing the first velocity during the first dispensing event to the second velocity during the second dispensing event; and

determining that the first dispensing event includes an occurrence of the air shot event when the first velocity is greater than the second velocity.

25. At least one machine-accessible storage medium having stored thereon instructions, which when executed by a machine cause the machine to perform operations comprising:

measuring dispensing events of a fluid from a medication injection device with a dosage tracking system, including:

measuring motion of the medication injection device with an accelerometer;

tracking data indicative of the dispensing events and the motion of the medication injection device output from the dosage tracking system with a controller coupled to the dosage tracking system; and

determining based on the data whether one or more of the dispensing events includes an air shot event, including:

identifying a rolling motion of the medication injection device, based on the motion of the medication injection device as a fluid mixing event; and

determining that a next one of the dispensing events following the fluid mixing event includes an occurrence of the air shot event.

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